BIOTECH PATENT ELIGIBILITY: A NEW HOPE

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The practical effect of the Supreme Court's decisions in Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Alice Corporation Pty. v. CLS Bank International has been to deny patent eligibility to innovative patent applications and patents, particularly in the fields of biotechnology and computer software. On July 5, 2016, the Federal Circuit in Rapid Litigation Management Ltd. v. CellzDirect, Inc. ruled that the claimed methods of cryopreserving hepatocyte cells are patent eligible under 35 U.S.C. § 101 because they are not directed to a natural phenomenon. The patentees discovered that some cells in a hepatocyte pool could survive multiple freeze-thaw cycles. The claims recite a method of producing a preparation of hepatocytes that can be frozen and thawed at least twice. The method steps include freezing and thawing a sample of hepatocytes, performing density fractionation to separate viable and non-viable cells, recovering the viable hepatocytes, and refreezing the recovered hepatocytes. The Federal Circuit decided that, although dependent on a natural phenomenon, the inventors' claims were a patent eligible application of their natural discovery. As a result, the court may have opened up a new avenue for patent seekers to circumvent the restrictive eligibility requirements established by the Supreme Court.

This Note provides a brief history of patent eligibility doctrine and the cases leading up to the decision in CellzDirect. It next analyzes the CellzDirect decision and its possible interpretations. Finally, it argues that this case represents an

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effort by the Federal Circuit to limit the Supreme Court's extreme anti-patent position in Mayo and Alice by cabining the eligibility restrictions to diagnostic discoveries.

I. INTRODUCTION

In an effort to prevent patents from "tying up the fundamental building blocks of science,"[1] the Supreme Court ruled in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* that a method of diagnostic testing to determine the optimal dosage of autoimmune disease drugs by monitoring certain metabolites in a patient's blood was invalid because it was directed to a law of nature.[2] Similarly, in order to deny patent protection for innovations that are fundamentally non-technological in nature, the Court ruled in *Alice Corp. v. CLS Bank International* that a method of mitigating settlement risk in financial transactions by using a computer system as a third-party intermediary was invalid for being directed to an abstract idea.[3] In doing so, it built upon the two-step framework for distinguishing a patent-ineligible concept from an *application* of the patent-ineligible concept. First, the Court must determine whether a patent claim at issue is "directed to" one of three patent-ineligible concepts—law of nature, natural phenomenon, or abstract idea.[4] Second, if the answer is yes, the court must then search for an "inventive

[1] Christopher M. Holman, *The* Mayo *Framework Is Bad for Your Health*, 23 GEO. MASON L. REV. 901, 911 (2016).

[2] Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66, 72 (2012).

[3] Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2351–52 (2014). For a brief history of eligibility doctrine, see Appendix, *infra*.

[4] *Alice*, 134 S. Ct. at 2355.

concept" that transforms the nature of the claim into a patent-eligible application.[5]

The practical effect of *Mayo* and *Alice* has been to deny patent eligibility to innovative patent applications and patents, particularly in the fields of biotechnology and computer software.[6] For example, this framework was used to deny patent eligibility for a non-invasive method of accessing fetal DNA using previously discarded cell-free cffDNA and a method for gene detection by amplifying and analyzing significantly shorter "non-coding regions known to be linked to the coding region" of interest.[7]

On July 5, 2016, however, the Federal Circuit in *Rapid Litigation Management v. CellzDirect, Inc.*, ruled that the claimed methods of cryopreserving hepatocyte cells were eligible under 35 U.S.C. § 101 because they were not directed to a natural phenomenon.[8] The claims recite a method of producing a preparation of hepatocytes "capable of being frozen and thawed at least two times."[9] The process consists of freezing and thawing a sample of hepatocytes, performing density fractionation to separate viable and non-viable cells, recovering the viable hepatocytes, and refreezing the recovered hepatocytes.[10] This method also allows for the previously impractical practice of pooling hepatocytes from different samples to create a heterogeneous sample.[11]

The Federal Circuit determined that although the "inventors certainly discovered the cells' ability to survive multiple

5 *Id.* at 2357.

6 *See generally* Warren Woessner, Rapid Litigation v. CellzDirect – *A Break in the Section 101 Wall*, NAT'L L. REV. (July 5, 2016), http://www.natlawreview.com/article/rapid-litigation-v-cellzdirect-break-section-101-wall [perma.cc/8P2S-7HMD]; Michael A. Sanzo, *The Patenting of Gene Based Diagnostic Assays in a Post* Mayo *and* Myriad *World*, 16 J. MARSHALL REV. INTELL. PROP. L. 1 (2016).

7 Ariosa v. Sequenom, 788 F.3d 1371 (Fed. Cir. 2015); Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369 (Fed. Cir. 2016).

8 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1044 (Fed. Cir. 2016).

9 *Id.* at 1046.

10 *Id.*

11 *Id.* at 1045–46.

freeze-thaw cycles . . . that is not where they stopped, nor is it what they patented."[12] Instead, the inventors "employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use."[13] As a result, the court may have created a new avenue for patent seekers to circumvent the restrictive eligibility requirements established by the Supreme Court.[14]

This Note provides a brief description of the Supreme Court's *Mayo*/*Alice* test and the Federal Circuit cases leading up to the decision in *CellzDirect*. It next analyzes the *CellzDirect* decision and its possible interpretations. Finally, it argues that this case represents an effort by the Federal Circuit to limit the Supreme Court's extreme anti-patent position in *Mayo* and *Alice* by cabining the eligibility restrictions to diagnostic discoveries.

II. THE RESTRICTION OF BIOTECHNOLOGY PATENT ELIGIBILITY

A. The *Mayo* and *Alice* Framework

Court decisions have articulated the *Mayo*/*Alice* test as a simple two-step inquiry in which the court first determines whether the claim at issue is "directed to" a natural phenomenon, law of nature, or an abstract idea.[15] If so, it next considers whether the elements of the claim, "individually [or] as an ordered combination . . . transform the nature of the claim into a patent-eligible application."[16]

1. Step One: Directed to a Patent-Ineligible Exception?

The first step of the *Mayo* and *Alice* analysis is to determine "whether the claims at issue are directed to one of [the]

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12 *Id.* at 1048.

13 *Id.*

14 Woessner, *supra* note 6.

15 *See, e.g.*, DDR Holdings, L.L.C. v. Hotels.com, 773 F.3d 1245, 1255 (Fed. Cir. 2014).

16 *Id.*

patent-ineligible concepts"—laws of nature, natural phenomena, and abstract ideas.[17] The Court in *Mayo* reasoned that "even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are 'the basic tools of scientific and technological work.'"[18] The Court was particularly worried about the danger in granting patents based on these concepts that would "tie up their use," thus preventing further innovation.[19] Despite this concern, the courts in *Bilski*, *Mayo*, *Myriad*, and *Alice* declined to elaborate on these categories themselves and instead simply asserted that the claims at issue were each directed at an ineligible concept.[20]

Similarly, Federal Circuit cases have done little to clarify this first step. In many patent eligibility cases, the Federal Circuit has quickly disposed of this step by simply declaring that the claim is directed to one of the exceptions.[21] However, a select number of cases do provide some guidance. In 2015, the Federal Circuit described a law of nature as "*exact* statements of physical relationships, deduced from scientific observations of natural phenomena . . . [and] often represented by equations."[22] In addition, cases such as *Ariosa* and

17 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) (citing Mayo Collab. Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 77 (2012)).

18 *Mayo*, 566 U.S. at 86 (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

19 *Id*.

20 Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-*Alice *Jurisprudence of Abstractions*, 16 N.C. J.L. & TECH. 647, 656 (2015); *see also Alice*, 134 S. Ct. at 2357 ("In any event, we need not labor to delimit the precise contours of the 'abstract ideas' category in this case. It is enough to recognize that there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here. Both are squarely within the realm of 'abstract ideas' as we have used that term."). *See generally* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013); Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66 (2012); Bilski v. Kappos, 561 U.S. 593 (2010).

21 *See* Jasper L. Tran, *Software Patents: A One-Year Review of* Alice v. CLS Bank, 97 J. PAT. & TRADEMARK OFF. SOC'Y 532, 542–44 (2015).

22 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1285 (Fed. Cir. 2015).

Association for Molecular Pathology v. Myriad Genetics, Inc. applied the natural phenomena category to nature-based products.[23] Furthermore, the Federal Circuit described an abstract-idea claim as an "ordered combination of steps [that] recites an abstraction—an idea, having no particular concrete or tangible form."[24] This includes "mathematical algorithms, including those executed on a generic computer, . . . [and] some fundamental economic and conventional business practices."[25]

2. Step Two: Significantly More than the Exception Itself?

The Supreme Court described the second step of the framework as a "search for an 'inventive concept.'"[26] A patent claim directed to an ineligible concept can survive if it contains "an element or combination of elements that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"[27] This second step is crucial because, as the *Mayo* decision noted, "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas."[28] Additionally, the *Mayo* Court emphasized that a mere recitation of a law of nature with the directive to "apply it" appended to the end is not deserving of patent protection.[29] Unfortunately, the Court has declined to

[23] *See, e.g.*, Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2110–11 (2013).

[24] Ultramercial, Inc. v. Hulu, L.L.C., 772 F.3d 709, 715 (Fed. Cir. 2014).

[25] DDR Holdings, L.L.C. v. Hotels.com, 773 F.3d 1245, 1256 (Fed. Cir. 2014).

[26] Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2355 (2014) (quoting Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66, 80–81 (2012)).

[27] *Id*.

[28] *Mayo*, 566 U.S. at 71.

[29] *Id*. at 72.

elaborate on the "inventive concept" necessary beyond establishing the "apply it" floor.[30]

The Federal Circuit has not been able to do much to simplify the inquiry.[31] For example, in *Ultramercial, Inc. v. Hulu, L.L.C.*, the Federal Circuit applied a seemingly endless number of tests gathered from all of the Supreme Court's precedents to determine that Ultramercial's claim of offering copyrighted media to consumers in exchange for watching advertisements was "an abstract idea, devoid of a concrete or tangible application."[32] The court decided that the additional features were well understood, routine, or conventional; the steps were specified at a high level of generality; the steps were merely data gathering steps; the claims only represented insignificant pre-solution activity; the process was just a drafting effort designed to monopolize the abstract idea itself; and the fact that the steps were limited to a technological arena where it was not previously employed and the concept's application to the Internet was not enough to pass the machine or transformation test.[33] In addition, because of the Supreme Court's vagueness, there is a potential for a new test or factor to examine in the second step of the *Mayo*/*Alice* framework with every new § 101 case.[34]

B. The Federal Circuit Post-*Alice*

Although the two-step analysis test is vague, the Federal Circuit has used it to invalidate most of the patents before it on eligibility grounds.[35] Post-*Alice,* it had held every chal-

30 Lefstin, *supra* note 20, at 656.

31 John M. Golden, Flook *Says One Thing,* Diehr *Says Another: A Need for Housecleaning in the Law of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1765, 1772 (2014).

32 Ultramercial, Inc. v. Hulu, L.L.C., 772 F.3d 709, 715 (Fed. Cir. 2014).

33 *Id.* at 716. *See also* Lefstin, *supra* note 20, at 657.

34 *See* Golden, *supra* note 31, at 1772.

35 U.S. PATENT AND TRADEMARK OFFICE, CHART OF SUBJECT MATTER ELIGIBILITY COURT DECISIONS (2017) [hereinafter ELIGIBILITY COURT DECISIONS], https://www.uspto.gov/sites/default/files/documents/ieg-sme_crt_dec.xlsx [perma.cc/235Z-SUJ2]; Tran, *supra* note 21, at 541; Jasper L.

lenged biotechnology patent ineligible until *CellzDirect*.[36] In the period between *Alice* and *CellzDirect*, the Federal Circuit reviewed twenty-five cases on § 101 grounds and found all but three ineligible.[37] While this Note focuses on biotechnology patents, it is important to take a quick look at the three computer patents that were held eligible between *Alice* and *CellzDirect* because the *Alice* Court suggested that abstract ideas and laws of nature may be similarly evaluated.[38]

1. Before *CellzDirect*, Only Three Federal Circuit § 101 Cases Found a Patent Eligible

The Federal Circuit first held a post-*Alice* patent eligible in *DDR Holdings, L.L.C. v. Hotels.com*.[39] The claims at issue were directed at the practice of generating websites that can "display a third-party merchant's products, but retain its visitor traffic by displaying this product information from within a generated web page that 'gives the viewer of the page the impression that she is viewing pages served by the host' website."[40]

Interestingly, the *DDR Holdings* court found that the claims cleared the § 101 hurdle in an analysis of the second step of the *Alice*/*Mayo* framework, but declined to identify in the first step the precise nature of the abstract idea underlying the claims.[41] The Federal Circuit's finding of an inventive concept seems to expand on language in *Alice* that claims can be patent eligible if they "effect an improvement

Tran, *Two Years After* Alice v. CLS Bank, 98 J. PAT. & TRADEMARK OFF. SOC'Y 354, 359 (2015).

36 *See* ELIGIBILITY COURT DECISIONS, *supra* note 35.

37 *See, e.g.*, DDR Holdings, L.L.C. v. Hotels.com, 773 F.3d 1245 (Fed. Cir. 2014); Enfish, L.L.C. v. Microsoft Corp., 822 F.3d 1327 (Fed. Cir. 2016); BASCOM Glob. Internet Servs. v. AT&T Mobility, 827 F.3d 1341 (Fed Cir. 2016). *See also* ELIGIBILITY COURT DECISIONS, *supra* note 35 (comparing recent Federal Circuit decisions under § 101).

38 Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2357 (2014).

39 *DDR Holdings*, 773 F.3d at 1255.

40 *Id.* at 1249. (quoting U.S. Patent No. 6,629,135, col. 2 ll. 56–63, col. 3 ll. 20–22).

41 *Id.* at 1256–57, 1259.

in [a] . . . technology or technical field."[42] It reasoned that rather than "broadly and generically claim[ing] 'use of the Internet' to perform an abstract business practice (with insignificant added activity) . . . the claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks."[43] This seems to add yet another test to be considered in the *Alice*/*Mayo* second step: whether the claims solve a specific problem "rooted in" a particular technology.

The next patent to be upheld by the Federal Circuit did not come until 2016—almost two years after *Alice*—in *Enfish, L.L.C. v. Microsoft Corp*.[44] The court seemed to diverge from previous cases by declaring that the two-step "formulation plainly contemplates that the first step of the inquiry is a meaningful one . . . because essentially every routinely patent-eligible claim involving physical products and actions *involves* a law of nature and/or natural phenomenon."[45] For the first time, the Federal Circuit ruled that a challenged patent was not an abstract idea at all.[46]

First, the court embraced the idea that the abstract-idea category has not been defined and "found it sufficient to compare claims at issue to those claims already found to be directed to an abstract idea in previous cases."[47] In *Enfish*, the invention "improve[d] upon prior art information search and retrieval systems by employing a flexible, self-referential table to store data."[48] Although the Supreme Court in *Alice* discussed improvements to a computer's function or an existing technological process in its second step of the *Mayo* analysis, the Federal Circuit declined to view *Alice* as "broadly

42 *Alice*, 134 S. Ct. at 2359.

43 *DDR Holdings*, 773 F.3d at 1257–58.

44 Enfish, L.L.C. v. Microsoft Corp., 822 F.3d 1327, 1346 (Fed. Cir. 2016).

45 *Id.* at 1335.

46 Tran, *supra* note 35, at 365.

47 *Enfish*, 822 F.3d at 1334.

48 *Id.* at 1337.

hold[ing] that all improvements in computer-related technology are inherently abstract."[49]

Second, the Federal Circuit found that "the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity."[50] Accordingly, it found the claims to not be directed to an abstract idea and upheld the patent.[51] It is important to note that the court warned that "describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule."[52]

While *Enfish* provides an explanation of *Alice*'s first step, the next opinion to uphold a patent provides insight into the second step.[53] In *BASCOM v. AT&T*, the Federal Circuit analyzed the eligibility of an internet-content filtering system.[54]

The claimed filtering system is located on a remote Internet Service Provider ("ISP") server that associates each network account with (1) one or more filtering schemes and (2) at least one set of filtering elements from a plurality of sets of filtering elements, thereby allowing individual network accounts to customize the filtering of Internet traffic associated with the account.[55]

The district court previously invalidated the patent as directed to the abstract idea of "filtering content" because it found internet content to be akin to any other medium, such as books, magazines, television, or movies.[56]

The Federal Circuit vacated and remanded based on the second step of the *Mayo*/*Alice* test.[57] Surprisingly, it cited

49 *Id.* at 1335.

50 *Id.* at 1336.

51 *Id.*

52 *Id.* at 1337.

53 *See* BASCOM Glob. Internet Servs. v. AT&T Mobility, 827 F.3d 1341 (Fed Cir. 2016).

54 *Id.* at 1343.

55 *Id.* at 1345.

56 *Id.* at 1346–47.

57 *Id.* at 1352.

Enfish for the proposition that in computer-related claims in which there are "close calls about how to characterize what the claims are directed to . . . [the] analysis of whether there are arguably concrete improvements in the recited computer technology could take place under step two."[58] The court recognized that the claims were directed to filtering Internet content, but it found that filtering content in and of itself is an abstract idea.[59] Thus, the court skipped the first step of the test because the claims here were not "unambiguously directed to an improvement in computer capabilities," as they were in *Enfish*.[60]

In its analysis of the second step, the court agreed "with the district court that the limitations of the claims, taken individually, recite generic computer, network and Internet components, none of which is inventive by itself."[61] However, it also recognized that "an inventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces."[62] Thus, it found that the patent described an inventive concept because it recites "a specific, discrete implementation of the abstract idea of filtering content . . . and the patent describes how its particular arrangement of elements is a technical improvement over prior art ways of filtering such content."[63] The court analogized the claims to those in *DDR Holdings*, because BASCOM also claimed a technology-based solution, in this case, "to filter content on the Internet that overcomes existing problems with other Internet filtering systems."[64]

58 *Id.* at 1348 (quoting Enfish, L.L.C. v. Microsoft Corp., 822 F.3d 1327, 1339–40 (Fed. Cir. 2016)) (internal quotation marks omitted).

59 *Id.*

60 *Id.* at 1349.

61 *Id.*

62 *Id.* at 1350.

63 *Id.*

64 *Id.* at 1351.

III. *RAPID LITIGATION V. CELLZDIRECT* TO THE RESCUE?

With the *Enfish* and *BASCOM* cases, the Federal Circuit set the stage for the fourth post-*Alice* case upholding a patent—this time in relation to the laws of nature in the biotechnology sphere. In *Enfish*, the court established that a patent can survive the § 101 threshold if the claims are "unambiguously directed to a technological improvement" and thus not an abstract idea or law of nature.[65] If the "directed to" question is a "close call" in step one, *BASCOM* allows inventors to argue that the patent is eligible under step two by showing that the specific arrangement of elements in the claim amounts to an improved technological process.[66] Thus, in the software context, the steps seem to have collapsed into one because a computer is itself a technological innovation. Software that improves computer function or solves a computer-specific problem will pass the test. However, the Federal Circuit left open the question of what to do if a biological discovery improves some bodily function or solves a specific biomedical problem.

A. The Case: The Federal Circuit Strikes Back

1. The Claims At Issue in *CellzDirect*

Hepatocytes are a type of liver tissue used extensively for "biomedical research, including a variety of biological, pharmacological, and toxicological studies."[67] For example, hepatocytes can be used as model systems for the study of liver functions including drug toxicity and efficacy.[68] However, these model systems are limited because "fresh hepatocytes can only be obtained from liver resections or non-transplantable livers of organ donors, and their lifespan is

65 Tran, *supra* note 35, at 370.

66 *Id*.

67 Edward L. LeCluyse & Eliane Alexandre, *Isolation and Culture of Primary Hepatocytes from Rescued Human Liver Tissue*, *in* 640 METHODS IN MOLECULAR BIOLOGY 57, 57 (John M. Walker ed., 2010).

68 U.S. Patent No. 7,604,929 col. 1 ll. 37–39 (filed Oct. 20, 2009).

short . . . Supply is thus erratic, making availability limited and unpredictable."[69] Extant cryopreservation techniques to freeze these cells for later use led to cell damage and poor recovery rates of viable cells once thawed.[70] "These methods generally comprised freezing hepatocytes at frigid temperatures; then, when needed, thawing them and recovering the viable cells using density gradient fractionation."[71]

In addition, "[b]ecause hepatocytes from different donors generally have different metabolic properties, researchers desired to pool hepatocytes from various source livers" to study cells with varied liver-enzyme expression.[72] However, not only did the prior preservation method lead to poor recovery, but the need for donated cells to be preserved immediately made producing pooled samples from multiple donors difficult.[73] Moreover, although the cells could be mixed after thawing several frozen samples, the existing belief that the hepatocytes could only be frozen once led to the presumption that the entire resulting pool had to be used immediately.[74]

The inventors "discovered that some fraction of hepatocytes [is] capable of surviving multiple freeze-thaw cycles."[75] Using this discovery, they developed a process for making a mixed population of frozen hepatocytes with heightened viability.[76] Claim 1 of the '929 patent recites:

> 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes, being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:

69 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1045 (Fed. Cir. 2016).

70 *Id.*

71 *Id.*

72 *Id.*

73 *See* '929 Patent col. 3. ll. 5–8, 50–53.

74 *See id.* at col. 3. ll. 49–56.

75 *CellzDirect*, 827 F.3d at 1045.

76 *Id.*

> (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,
> (B) recovering the separated viable hepatocytes, and
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.[77]

2. The District Court Decision

The district court employed the *Alice* two-step method and invalidated the patent.[78] It found that "the patent recites the natural law that certain hepatocytes are capable of being frozen and thawed more than once."[79] In analyzing the inventive concept step, the court ruled that the multiple freezing steps were insufficient to transform the process into patentable material.[80] It reasoned that because the patentee "reapplied a well-understood freezing process," the claim "amount[ed] to a straightforward application of the truth that hepatocytes are inherently capable of surviving multiple freeze-thaw cycles."[81]

3. The Federal Circuit Decision

The Federal Circuit vacated and remanded. At step one, the court decided the claims were not "directed to" the natural phenomenon that some hepatocyte cells can survive multiple freeze-thaw cycles.[82] Although the innovation rests on

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77 '929 Patent col. 19 ll. 56–63, col. 20 ll. 12–20.

78 *See* Celsis in Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 783 (N.D. Ill. 2015).

79 *Id.*

80 *Id.* at 784.

81 *Id.*

82 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed. Cir. 2016).

this ability of hepatocytes to be frozen twice, the court recognized "that the claims are simply not *directed to* the ability of hepatocytes to survive multiple freeze-thaw cycles."[83] It found that these claims "are directed to a new and useful laboratory technique for preserving hepatocytes."[84] "This type of constructive process, carried out by an artisan to achieve 'a new and useful end,' is precisely the type of claim that is eligible for patenting."[85] It noted that "[t]he resulting preparation, and the process for creating it, achieved a notable advance over prior art techniques for preserving hepatocytes."[86] The court contended that, rather than simply claiming their discovery, the inventors "employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use."[87] It distinguished these claims from patent-ineligible concepts that "amounted to nothing more than observing or identifying the ineligible concept itself."[88]

The court also warned that almost any process can be described in terms of natural laws, which would allow a court to

> find patent-ineligible methods of, say, producing a new compound (as directed to the individual components' ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin).[89]

According to the court, this reasoning was especially relevant to claim 5, "which requires the additional step of pooling cells from multiple donors," because it "results in a prep-

83 *Id.* (emphasis added).

84 *Id.*

85 *Id.* (citing Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014)).

86 *Id.* at 1047.

87 *Id.* at 1048.

88 *Id.*

89 *Id.* at 1049.

aration that is both new and vastly more useful for research than hepatocyte preparations made by conventional methods."[90] Although the hepatocyte pool itself may not be patent eligible, the court ruled that this case was distinguishable from the multi-strain bacteria mixture at issue in *Funk Bros.* because the patent was not a resulting product, but rather the process of creating one.[91]

Even if it were directed to a natural phenomenon, the Federal Circuit argued that the patent improves an existing technological process sufficiently to "transform the process into an inventive application" of the phenomenon.[92] It is "eligible because it applies the discovery that hepatocytes can be twice frozen to achieve a new and useful preservation process."[93] Further, under *Diamond v. Diehr*, "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made."[94] The *CellzDirect* court focused on the fact that "the prior art taught away from multiple freezing steps,"[95] and that "[r]epeating a step that the art taught should be performed only once can hardly be considered routine or conventional."[96] The particular "combination of steps" as an application of a natural discovery here, as in *Diehr*, created a patentable claim.[97]

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90 *Id.*

91 *Id.* at 1049–50 ("It is the *process* of preservation that is patent eligible here, not necessarily the end product. In any event, LTC's argument proves too much: if LTC were correct, no one could ever get a patent on cryopreservation, or on any other innovative method that acts on something that is naturally occurring, simply because of the nature of the underlying subject matter.").

92 *Id.* at 1050 (citing Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014)).

93 *Id.* at 1050–51.

94 Diamond v. Diehr, 450 U.S. 175, 188 (1981).

95 *CellzDirect*, 827 F.3d at 1052 (quoting Celsis in Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 928 (Fed. Cir. 2012)).

96 *Id.* at 1051.

97 *Id.* at 1051 (quoting *Diamond*, 450 U.S. at 188).

Finally, the court conceded that once the inventor discovered that some cells could survive multiple freeze-thaw cycles, the task of refreezing the viable cells might have been simple or obvious.[98] Still, the "ease of execution or obviousness of application" is not a factor in the § 101 analysis but rather a question to be asked under other Patent Act provisions.[99] The court also noted that the patent at issue does not run into the preemption problems that served as the central policy consideration that "undergirds . . . § 101 jurisprudence."[100] It recognized that the patent "does not lock up the natural law in its entirety" and that "LTC has already managed to engineer around the patent."[101] This marked the first sign of relief from the Federal Circuit in the life sciences arena but, as discussed in Part IV, infra, the holding can be interpreted many ways.[102]

IV. THE DECISION SAVES BIOTECHNOLOGY PATENTS EXCEPT FOR DIAGNOSTICS

The Federal Circuit validated the hepatocyte cryopreservation method by plainly stating that the claim was not "directed to" a natural phenomenon because it was not merely the discovery that hepatocytes can be frozen twice.[103] It also held that even if it were, the patent presented an unconventional "combination of steps" because the prior art taught away from freezing twice.[104] Some see this decision as a turning point for the life sciences industry.[105] Broadly inter-

98 *Id.* at 1052.

99 *Id.*

100 *Id.* (quoting Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2358 (2014)).

101 *Id.* (quoting Celsis in Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 785 (N.D. Ill. 2015)).

102 *See* Gene Quinn, *Federal Circuit Gives Patent Eligibility Relief to Life Sciences Sector*, IPWATCHDOG (Jul. 5, 2016), http://www.ipwatchdog.com/2016/07/05/federal-circuit-patent-eligibility-life-sciences [perma.cc/JFJ4-BY5J].

103 *CellzDirect*, 827 F.3d at 1048.

104 *Id.* at 1051 (quoting Diamond v. Diehr, 450 U.S. 175, 188 (1981)).

105 *See* Quinn, *supra* note 100.

preted, the language in this decision can be used to find eligible all of the biotechnology patents the circuit previously invalidated. However, interpreted narrowly, this decision does not even apply to any of the precedent. This Section suggests that the former is the correct reading and the Federal Circuit is essentially cabining *Mayo's* extreme anti-patent reach from anything except for diagnostic methods that do not also include a method of treatment.

A. A New Explanation of the *Mayo*/*Alice* Test

1. Eligible As Long As the Claim Is Not "Directed to" the Natural Law

According to *CellzDirect*, courts should use the plain claim language to make the "directed to" determination.[106] "At step one, therefore, it is not enough to merely identify a patent-ineligible concept underlying the claim; the court must determine whether that patent-ineligible concept is what the claim is 'directed to.'"[107] Thus, the broadest interpretation of *CellzDirect* would allow patentees to skirt around the eligibility rules by arguing that a patent is directed to anything other than the diagnostic discovery. For example, one could try to argue that because they include a specific metabolite range to indicate efficacy, the claims in *Mayo* were directed to a new and useful method of treatment rather than merely the correlation between the drug and its metabolites. This of course would be preposterous because the patent in *Mayo* did not actually contain a treatment step to implement once the effective dosage had been calculated. A patentee could also potentially use clever claim drafting, but this would surely go against the Supreme Court's worry in *Parker v. Flook* that "mak[ing] the determination of patentable subject matter depend simply on the draftsman's art . . . would ill serve the principles underlying the prohibition against patents for 'ideas' or phenomena of nature."[108]

106 *CellzDirect*, 827 F.3d at 1050.

107 *Id.*

108 Parker v. Flook, 437 U.S. 584, 593 (1978).

Therefore, this decision can be interpreted as holding patents eligible as long as the end result is not just information or a mental step such as comparing, determining, or detecting. In fact, the court stated that "comparing two sequences to detect alterations is a patent-ineligible 'abstract mental process.'"[109] It added that although claims may employ method steps, if "the end result of the process, the essence of the whole, [i]s a patent-ineligible concept" the claims fall under the first step in *Mayo*.[110] This would invalidate most diagnostics where the end result is detection of a disease. Of course, the narrowest interpretation could be that the hepatocyte preservation patent is only eligible because the end result is a tangible product; therefore, all diagnostics would be invalid—with the exception of self-contained diagnostic kits. However, neither the Supreme Court nor the Federal Circuit has suggested that diagnostics are categorically ineligible. This leaves a middle ground between a pure diagnostic method and a manufacturing method.

In *CellzDirect*, "[t]he inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented."[111] Thus, the fractioning step in the hepatocyte preservation is analogous to a diagnostic method. Discovering that some cells are viable following a second freeze-thaw step and sorting the viable cells by gradient fractionation is akin to discovering a genetic marker for a disease and screening patients based on the marker. However, according to the Federal Circuit, the inventor cannot stop there.[112] This suggests that an inventor must apply some sort of treatment to these sorted patients to escape the "directed to" analysis of the *Mayo*/*Alice* test.

2. Eligible if the Claimed Method Goes Against

109 *CellzDirect*, 827 F.3d at 1048 (quoting *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 763 (Fed. Cir. 2014)).

110 *Id.*

111 *Id.*

112 *See id.*

the Prior Art

Even if the fact that the end result of a claim is not a tangible product places the claim into a judicial exception in the first *Mayo*/*Alice* step, the *CellzDirect* analysis under the second step could still give patent eligibility relief to diagnostic tests. The court states that "the individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine and conventional."[113] It noted that the prior art in hepatocyte preservation taught away from a second freezing step.[114] Even though adding a novel unconventional limitation would allow a patent directed to a judicial exception to be eligible under *Mayo*, the *CellzDirect* court stated that the obviousness of application should not be a consideration under § 101.[115] This is a looser standard than the "significantly more" standard set out in *Mayo*.[116] Under this reading, making a diagnosis and applying a well-known or obvious treatment would be enough to survive the second hurdle. Indeed, *CellzDirect* suggests that a claim could bypass the substantial step test as long as it "does not lock up the natural law in its entirety."[117] It further noted the fact that the would-be infringer already managed to engineer around the patent tilts in favor of patent eligibility.[118]

B. The USPTO's Response: Nothing Has Changed

In response to the *CellzDirect* case, the U.S. Patent and Trademark Office (the "USPTO") issued a memorandum to address the case's effect on the USPTO's current subject

113 *Id.* at 1051.

114 *Id.*

115 *Id.* at 1052.

116 *See* Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66, 77 (2012).

117 *CellzDirect*, 827 F.3d at 1052 (quoting Celsis in Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 785 (N.D. Ill. 2015)).

118 *Id.* (quoting Celsis in Vitro, Inc. v. CellzDirect, Inc., 83 F. Supp. 3d 774, 785 (N.D. Ill. 2015)).

matter eligibility guidance and training examples.[119] The memo noted that the decision's emphasis on the need to scrutinize the claims' focus in the "directed to" analysis in step one is consistent with *Enfish*.[120] The USPTO also reiterated that "these claims that apply a law of nature are distinguishable from the claims in *Mayo* and *Sequenom* that were found to be directed to a patent-ineligible concept when they 'amounted to nothing more than observing or identifying the ineligible concept itself.'"[121] Finally, the USPTO wrote that its "current subject matter eligibility guidance . . . and training examples are consistent with these points."[122]

Interestingly, the USPTO examples in its guidelines indicate that it has already adopted the anti-diagnostic position suggested by this Note.[123] In the example of a patent for diagnosing disease, the guidelines state that a method of diagnosing a diseased patient by detecting the presence of a certain protein in the plasma sample is ineligible.[124] However, a method of diagnosing the disease is eligible where it includes detection of a protein using a particular antibody or treatment of the diagnosed patient using a known drug in the field.[125] The guidelines further state that "[t]he totality of these steps including the recitation of a particular treatment . . . integrate the exception into the diagnostic and treatment process, and amount to more than merely diagnosing a patient . . . and instructing a doctor to generically 'treat it.'"[126] This accords with the above interpretation of *CellzDirect* that

119 ROBERT W. BAHR, U.S. PATENT AND TRADEMARK OFFICE, MEMORANDUM: RECENT SUBJECT MATTER ELIGIBILITY RULINGS (July 14, 2016) [hereinafter RAPID MEMO], https://www.uspto.gov/sites/default/files/documents/memo_rlm-sequenom.pdf [perma.cc/L6QY-5YFT].

120 *Id.* at 2.

121 *Id.*

122 *Id.*

123 *See* U.S. PATENT AND TRADEMARK OFFICE, SUBJECT MATTER ELIGIBILITY EXAMPLES: LIFE SCIENCES (May 4, 2016) [hereinafter EXAMPLES: LIFE SCIENCES], https://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf [perma.cc/Z57M-HNXX].

124 *Id.* at 11–12.

125 *Id.* at 13–16.

126 *Id.* at 15.

while a method of diagnosis alone is ineligible, a method of treatment in which diagnosis is merely a step is eligible.

Furthermore, in another training example, the USPTO guidelines state that a method for comparing a subject's DNA sequence and wild-type sequences, in which differences indicate an alteration in a certain gene, is ineligible.[127] It reasons that such a method is directed to a natural law because there is no limit on how the comparison is performed.[128] Thus, it relies on the mental step distinction contemplated by *CellzDirect*. The USPTO also would hold ineligible a claim for detecting conformational changes indicative of a mutation that only entails "hybridizing a wild-type probe" to the sample.[129] However, the guidelines further note that a claim in which the detection of conformational changes uses scanning near-field optical microscopy ("SNOM") would be eligible because SNOM, although known at the time, was not actually routinely or conventionally used.[130] The claim still contains the mental step that conformational changes are indicative of an alteration, but under the guidelines, the simple addition of SNOM would be a significant addition to the natural law.[131] The USPTO would similarly find eligible a method of analysis by using a sequencing method that was non-routine or unconventional at the time, such as Cool-Melt PCR.[132] Notably, the guidelines do not require that the hybridization techniques be completely novel, but rather just unconventional.[133] Without a definition of unconventional, this analysis could eventually stretch so that simply specifying the method of analysis would suffice.[134]

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127 *Id.* at 25.

128 *See id.*

129 *Id.* at 26.

130 *Id.*

131 *Id.* at 26.

132 *See id.* at 27–28.

133 *Id.* at 23.

134 Perhaps this is unsurprising because, according to *Mayo*, the steps of administering a drug to a patient and determining the resultant level of metabolite in the patient "are not themselves natural laws." Mayo Collab-

C. Subsequent Decisions: Return of *Mayo*

As of September 1, 2017, five of the thirty-nine patents reviewed by the Federal Circuit on § 101 grounds post *CellzDirect* have been found eligible.[135] All related to computer software and abstract ideas.[136] Four escaped § 101 ineligibility on the first "directed to" prong of the *Mayo*/*Alice* test.[137] The court used the reasoning found in *Enfish* that patents "focus[ing] on a specific means or method that improves the relevant technology" are eligible to validate patents for animating lip synchronization and facial expressions by coding rules into a computer,[138] creating a graphical user interface to prevent ordering of financial instruments at a changed price,[139] tracking more efficiently an object on a moving platform by tracking motion relative to the platform rather than the Earth,[140] and creating a universal computer memory system with programmable characteristics based on the processor.[141] The fifth—a system allowing network pro-

orative Servs. v. Prometheus Labs., 566 U.S. 66, 67 (2012). It seems inconsonant to hold as a natural law the steps of hybridizing a probe to a specific DNA sequence and determining the resultant conformational changes.

135 ELIGIBILITY COURT DECISIONS, *supra* note 35. *See also* McRO, Inc. v. Bandai Namco Games Am. Inc., 837 F.3d 1299 (Fed. Cir. 2016); Amdocs (Israel) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288 (Fed. Cir. 2016); Trading Techs. Int'l v. CQG Inc., 675 Fed. Appx. 1001 (Fed. Cir. 2017); Thales Visionix Inc. v. United States, 850 F.3d 1343 (Fed. Cir. 2017); Visual Memory L.L.C. v. Nvidia Corp., 867 F.3d 1253 (Fed Cir. 2017); Jason Rantanen, BASCOM v. AT&T*: Section 101 Jurisprudence Continues to Develop*, PATENTLYO (July 19, 2016), http://patentlyo.com/patent/2016/07/jurisprudence-continues-develop.html [perma.cc/T6L6-QLU8].

136 ELIGIBILITY COURT DECISIONS, *supra* note 35.

137 *McRO*, 837 F.3d at 1316; *Trading Techs.*, 675 Fed. Appx. at 1006; *Thales*, 850 F.3d at 1349; *Visual Memory*, 867 F.3d at 1262.

138 *McRO*, 837 F.3d at 1307–08, 1314 (citing Enfish, L.L.C. v. Microsoft Corp., 822 F.3d 1327, 1336 (Fed. Cir. 2016)).

139 *Trading Techs.*, 675 Fed. Appx. at 1003.

140 *Thales*, 850 F.3d at 1344–45.

141 *Visual Memory*, 867 F.3d at 1256.

viders to account and bill for network communications—recited an inventive concept, according to the court.[142]

1. *Cleveland Clinic Foundation v. True Health Diagnostics*

While the Federal Circuit has run with *Enfish* and *BASCOM* to find several computer patents eligible, the same has not happened in biotechnology cases. The only biotech case heard by the court in the same period was *Cleveland Clinic Foundation v. True Health Diagnostics*.[143] In essentially a *Mayo* redux, the court found ineligible a patent claiming methods for detecting myeloperoxidase ("MPO") in patients and correlating the results to cardiovascular risk.[144] Similar to the detection of metabolite levels in *Mayo*, the patentees collected MPO data from a large population to come up with a control value to determine a test subject's risk of disease.[145] The patent claims consisted of

> [a] method of assessing a test subject's risk . . . comprising comparing levels of [MPO] in a bodily sample . . . with levels . . . in comparable bodily samples from control subjects . . . wherein the levels of [MPO] . . . relative to the levels . . . from control subjects is indicative of the extent of the test subject's risk of having atherosclerotic cardiovascular disease.[146]

The court found that the "patents are directed to multistep methods for observing the law of nature that MPO correlates to cardiovascular disease."[147] The patentees attempted to analogize to the hepatocyte preservation technique in *CellzDirect* by arguing that the steps of isolating, quantifying, and comparing the amount of detected MPO to a control

142 Amdocs (Israel) Ltd. v. Openet Telecom, Inc., 841 F.3d 1288, 1306 (Fed. Cir. 2016).

143 Cleveland Clinic Found. v. True Health Diagnostics, 859 F.3d 1352 (Fed. Cir. 2017).

144 *Id.* at 1355, 1363.

145 *Id.* at 1362.

146 *Id.* at 1356.

147 *Id.* at 1360.

were "man-made endeavors building upon the natural law."[148] The court disagreed and held that the claims were not directed to a "new and useful laboratory technique," as was the case in *CellzDirect*.[149] The patent then failed step two of the analysis because the claims "require only conventional MPO detection methods and compare those values to . . . values derived from conventional statistical methods."[150]

Although three of the method claims in this case were ineligible because of their similarity to those in *Mayo*, a fourth claim was not. The distinguishing aspect of this claim was a step that requires "administering a lipid lowering agent to the selected human patient."[151] As noted earlier, however, a claim with this level of specificity is not very valuable. For instance, the infringement claim in *Cleveland Clinic* was dismissed because defendant lab's actions were limited to detecting and reporting MPO levels and did not extend to the actual treatment.[152] Because doctors rather than the labs are the parties responsible for ultimately administering treatments, the labs are immune to direct infringement suits.[153] Furthermore, most diagnostic patentees would not want to risk alienating physicians by suing them. Thus, although a patent claiming a diagnostic method that includes an actual treatment step can escape the "directed to" filter in the § 101 doctrine, it is of limited value.

148 Reply Brief of Plaintiffs-Appellants at 17, Cleveland Clinic Found., v. True Health Diagnostics, 859 F.3d 1352 (Fed. Cir. 2017) (No. 16-1776).

149 *Cleveland Clinic*, 859 F.3d at 1362 (citing Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed. Cir. 2016)).

150 *Id.* at 1363–64.

151 *Id.*

152 *See id.* at 1364–65.

153 35 U.S.C. § 271(a).

V. IMPLICATIONS OF THE DECISION

A. Applying This Interpretation to Federal Circuit Precedent

Although the court and the USPTO assert that the *CellzDirect* decision is not contrary to the existing jurisprudence, the reasoning in that case can be applied to find eligible the biotechnology patents previously invalidated by the Federal Circuit. Before *CellzDirect*, the Federal Circuit heard three biotechnology cases post-*Alice*.[154] Using the reasoning of *CellzDirect*, an argument can be made that the two cases assessing patents not directed towards a diagnostic method should have been decided differently.

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, the patentees discovered the existence of cell-free fetal paternal cffDNA circulating in pregnant women's blood.[155] Because this cffDNA is easily accessed via the mother's blood, it made genetic analysis of the fetus safer.[156] The patent claimed "amplifying a paternally inherited nucleic acid from the serum or plasma sample and detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample."[157] It further claimed "certain methods of using cffDNA" by "performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid."[158] The Federal Circuit rejected these claims because the patentees had not "created or altered any of the genetic information encoded in the cffDNA."[159] The court determined that the claims were directed to the existence of cffDNA itself and that the ampli-

154 See ELIGIBILITY COURT DECISIONS, *supra* note 35. The cases are: *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test, 774 F.3d 775 (Fed. Cir. 2014); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015); and Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369 (Fed. Cir. 2016).

155 *Sequenom*, 788 F.3d at 1373.

156 *See id.*

157 *Id.* at 1374.

158 *Id.* at 1373–74.

159 *Id.* at 1376.

fication and analysis steps were well understood, conventional, and routine.[160]

However, because the actual claims were specific methods of analyzing a fetus's DNA using cffDNA, the court's holding seems to be an example of how almost any process can be described in terms of natural laws, something that *CellzDirect* warned against. This Note's suggested reading of *CellzDirect* would allow the patent to escape § 101 because the end result is a new method of analyzing fetal DNA and distinguishing it from the mother's DNA. Here, none of the claims are specifically directed to the cffDNA itself, but rather the detection of paternally inherited DNA. Further, there is no mental step that compares two genetic sequences or determines an indication of a disease.

Even if the patent fails step one for lack of a tangible end product, under the second step of analysis one can argue that because scientists never looked in maternal blood for cffDNA prior to the invention, the combination of conventional steps is enough to transform them into an inventive application. In this context, the steps comprising the analysis of cffDNA can hardly be considered conventional. Just as the prior art taught away from freezing hepatocytes twice in *CellzDirect*, the prior art here taught away from retaining the cffDNA in the first place.[161] It is important to note that the most obvious application of this method is in detecting—or diagnosing—certain genetic defects in the fetus. However, the patent claims at issue were not directed to any diagnostic step. They were directed to a novel application of the mother's blood—mainly detection and analysis of cffDNA.[162] In addition, the *CellzDirect* court specifically noted that the Supreme Court stated, "Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could have sought a method patent. But the processes used by Myriad to isolate DNA were well understood

160 *Id.* at 1377–78.

161 *Id.* at 1380.

162 *Id.* at 1375.

. . . and are not at issue in this case."[163] In *Sequenom*, the claims also detailed specific steps to distinguish and separate the cffDNA from the mother's DNA.[164] The method of isolating paternally inherited DNA by analyzing the cffDNA was not well understood or conventional. Thus, because the claims at issue are not diagnostic methods, the cffDNA patent should be held eligible under the suggested reading of *CellzDirect*.

Significantly, this is the outcome many of the Federal Circuit judges would have reached. Judge Linn, concurring, stated:

> I join the court's opinion invalidating the claims of the '540 patent only because I am bound by the sweeping language of the test set out in *Mayo* . . . In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.[165]

In addition, on petition for rehearing en banc, Judges Lourie, Moore, Dyk, and Newman agreed that the patents should not have been invalidated on § 101 grounds. In an opinion concurring with the denial of the petition for rehearing, Judge Lourie wrote that the claims "should not be patent-ineligible on the ground that they set forth natural laws or are abstractions."[166] Nevertheless, he concurred in denying the petition because he could "find no principled basis to distinguish this case from *Mayo*."[167]

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163 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1049 (Fed. Cir. 2016) (citing Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2119–20 (2013)).

164 *Sequenom*, 788 F.3d at 1374.

165 *Sequenom*, 788 F.3d at 1380 (Linn, J., concurring).

166 Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring) (denial of petition for rehearing en banc).

167 *Id.* at 1284.

In *Genetic Technologies v. Merial*—another case pertaining to a non-diagnostic method patent—the Federal Circuit invalidated claims directed to "[a] method for detection of at least one coding region allele of a multi-allelic genetic locus" by amplifying a linked non-coding region using generic DNA amplification techniques.[168] The inventors discovered the existence of these short non-coding regions, which allow much easier analysis of the longer linked coding regions. The court reasoned that the claims were "directed to a natural law—the principle that certain non-coding and coding sequences are in linkage disequilibrium with one another."[169]

The claims here were also devoid of any comparison steps but still did not result in a tangible end-product.[170] However, the patent claim can be considered the application of a fact—that linked non-coding regions can detect genes in the more complicated coding regions—to a method for detecting and analyzing genes. Further, according to the USPTO, the addition of a non-conventional PCR method, such as Cool-Melt PCR, to analyze a specific gene satisfies the § 101 hurdle.[171] In *Merial*, the use of linked non-coding regions is analogous to the Cool-Melt PCR method. It would follow that if this claim was directed to a new method of PCR, the standard method of gene amplification, it should survive the § 101 filter. Again, the end result here would not be information but a sample of amplified genes that can be later analyzed akin to the hepatocyte pools in *CellzDirect*.

In addition, the second step of *CellzDirect* applies to *Merial*. Before the discovery, the prior art taught away from analyzing the non-coding regions just as the prior art in hepatocyte preservation taught away from multiple freeze steps.[172] It is important to note that the Federal Circuit did not lament its finding of ineligibility as it did in *Sequenom*, which is likely explained by the fact that the question of

168 Genetic Techs. Ltd. v. Merial L.L.C., 818 F.3d 1369, 1373 (Fed. Cir. 2016).

169 *Id.* at 1377.

170 *See id.* at 1379.

171 EXAMPLES: LIFE SCIENCES, *supra* note 123.

172 *Merial*, 818 F.3d at 1373.

preemption loomed large in *Merial*.[173] However, the issue of whether claims are appropriately limited should be analyzed under requirements of patentability in § 112.[174]

Finally, applying the *CellzDirect* analysis to the lone diagnostic case, *In the matter of BRCA1- & BRCA2-Based Hereditary Cancer Test,* leads to ineligibility.[175] In *BRCA1 & BRCA2*, the natural discovery was that certain mutations in the BRCA genes are linked to increased risk of breast cancer.[176] Although the genes themselves were held unpatentable in *Myriad*, the claims at issue on remand in the Federal Circuit were methods which called for "comparing" a patient's BRCA gene with wild type BRCA genes using standard DNA replication techniques.[177] They further provided that "a difference in the sequence of the BRCA1 gene, BRCA1 RNA, or BRCA1 cDNA of the subject from wild-type indicates an alteration in the BRCA1 gene in said subject."[178] The court invalidated the claims and ruled that they "are directed to the patent-ineligible abstract idea of comparing BRCA sequences and determining the existence of alterations."[179] For the second step, the court found that the sequencing techniques "do nothing more than spell out what

[173] *Id.* at 1375 ("Claim 1 covers any comparison, for any purpose, of any non-coding region sequence known to be linked with a coding region allele at a multi-allelic locus . . . . Claim 1 broadly covers essentially all applications, via standard experimental techniques, of the law of linkage disequilibrium to the problem of detecting coding sequences of DNA.").

[174] Ariosa Diagnostics, Inc. v. Sequenom, Inc., 809 F.3d 1282, 1286 (Fed. Cir. 2015) (Lourie, J., concurring) (denial of petition for rehearing en banc) ("The claims might be indefinite or too broad in that they do not specify how to amplify and detect, or how to separate, detect, and diagnose. Or they perhaps attempt to claim all known methods of carrying out those steps. But the finer filter of § 112 might be better suited to treating these as questions of patentability, rather than reviewing them under the less-defined eligibility rules.").

[175] *In re* BRCA1- & BRCA2-Based Hereditary Cancer Test, 774 F.3d 755 (Fed. Cir. 2014).

[176] *Id.* at 758.

[177] *Id.* at 764.

[178] *Id.* at 762.

[179] *Id.* at 764.

practitioners already knew—how to compare gene sequences using routine, ordinary techniques."[180]

Under the anti-diagnostic interpretation of *CellzDirect*, the claims in *BRCA1 & BRCA2* could only be saved by adding a clause stating that the existence of a BRCA mutation indicates increased risk of breast cancer and suggesting some specific form of treatment for such patients. In this hypothetical, the patent would be akin to the method claims approved by *CellzDirect* and *Cleveland Clinic*. The treatment of patients with an increased risk of breast cancer can be considered the "new and useful end" of applying the natural law that BRCA mutations are linked to increased breast cancer risk.[181] In this way, the claims can be considered as not being directed to a patent-ineligible abstract idea but rather to a novel application of it. Of course, a patent claim this specific would be easy to circumvent and thus not very valuable.

B. The Problem with Denying Patent Eligibility to All Diagnostic Methods

Although the *CellzDirect* decision might help biotechnology patents that are not diagnostics, there remains tension over the disparity in decisions regarding diagnosis and treatment of disease. The former is "directed to" the natural law because of the relationship between an indication of a disease and the natural law that allows this diagnosis, while the latter is not "directed to" the natural law. Why is treating a disease considered a useful process but diagnosing one not? Seemingly the only difference is that a diagnosis amounts to a mental step. But what about a claim for a new way of treating a disease where the choice of drug depends on the diagnostic? Why can't the diagnostic step be the inventive step? Perhaps the USPTO and Federal Circuit could create a special category for diagnostics like they did for

180 *Id.* at 765.

181 Rapid Litig. Mgmt. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed. Cir. 2016) (quoting Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2354 (2014)).

products of nature in light of *Diamond v. Chakrabarty*.[182] However, without a Supreme Court case holding a diagnostic patent eligible akin to that in *Chakrabarty*, there would be no guidelines for evaluating this special category. Although some in the patent community would like to see this happen, because the Supreme Court has not made any indication of relaxing its restrictive standard in *Mayo*, speculation of this hypothetical category seems best left for a later day.[183]

VI. CONCLUSION

The Supreme Court, in its recent forays into patent eligibility, has taken an extremely anti-patent position by broadly applying the law of nature, natural phenomena, and abstract idea exceptions. While the Supreme Court presented a far-reaching test in *Mayo* and *Alice* that potentially invalidates any patent tied to discoveries in the life sciences on the basis of § 101, the Federal Circuit's decision in *Rapid Litigation Management v. CellzDirect, Inc.* seems to have given hope to the biotechnology industry. A plausible interpretation of the decision would limit the *Mayo*/*Alice* analysis to patents in which the end result is a mental step. This essentially restricts the test's invalidation reach to pure diagnostic methods. This would be consistent with the USPTO's guidelines and could lead to a separate analysis method for diagnostics much like the USPTO's treatment of products of nature. Whether the Supreme Court will approve of this development by the Federal Circuit is yet to be seen, but having recently denied certiorari in *Sequenom* and *CellzDirect*, the Court seems content to allow the Federal Circuit to continue to resolve this issue.[184]

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182 U.S. PATENT AND TRADEMARK OFFICE, SUBJECT MATTER ELIGIBILITY EXAMPLES: NATURE-BASED PRODUCTS (Dec. 16, 2014) [hereinafter EXAMPLES: NATURE-BASED PRODUCTS], https://www.uspto.gov/sites/default/files/documents/mdc_examples_nature-based_products.pdf [perma.cc/5XKL-6G2Q].

183 *See generally* Rebecca S. Eisenberg, *Diagnostics Need Not Apply*, 21 B.U. J. SCI. & TECH. L. 256 (2015).

184 Dennis Crouch, *Not Eligible: Supreme Court Denies All Pending Subject Matter Eligibility Petitions*, PATENTLYO (Oct. 3, 2016),

APPENDIX

A. The Development of Patent Eligibility Under § 101

Title 35 of the United States Code codifies patent law. § 101 defines the subject matter that may be patented: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[185]

The text of the statute requires that a patent be directed to one of four categories of acceptable subject matter: process (chemical, mechanical, or electrical procedures, such as a method for refining petroleum or a method embodied in a computer program), machine (mechanisms with moving parts, such as a motor), manufacture (man-made products, such as a hand tool), or composition of matter (chemical compounds, combinations, or mixtures, such as a plastic).[186] On its face, the statute takes an expansive view on patent eligibility. The categories are broad and modified by the unlimited word "any," and notably, the statute does not specify any ineligible categories.[187] This seemingly limitless threshold is, however, "subject to the conditions and requirements of th[e] title,"[188] namely novelty (that an invention be different from prior inventions and represent an advancement over prior knowledge),[189] non-obviousness (that a person of ordinary skill in the art presented with the prior art would not find the invention obvious),[190] and full disclosure (that a patent

http://patentlyo.com/patent/2016/10/eligible-eligibility-petitions.html [perma.cc/97K2-ZEF4].

185 35 U.S.C. § 101 (2012).

186 *See generally* Timothy A. Brisson & Victor Gallo, *Patent Law Basics*, NEV. LAW., Oct. 2000, at 10; Gary M. Ropski & Michael J. Kline, *A Primer on Intellectual Property Rights: The Basics of Patents, Trademarks, Copyrights, Trade Secrets and Related Rights*, 50 ALB. L. REV. 405 (1986).

187 35 U.S.C. § 101 (2012).

188 *Id.*

189 35 U.S.C. § 102 (2012).

190 35 U.S.C. § 103 (2012).

disclose the invention with adequate specificity).[191] The statute's structure differentiates eligibility from the remaining patentability requirements under Title 35.

Indeed, the Supreme Court clarified that § 101 is to be interpreted broadly, recognizing that Congress, when recodifying the Patent Act in 1952, intended its "wide scope"[192] to "include anything under the sun that is made by man."[193] Although the § 101 categories are expansive, the Supreme Court created three specific and narrow exceptions to patent eligible subject matter: the "laws of nature, physical [or natural] phenomena, and abstract ideas."[194]

1. Eligibility Prior to the 1952 Patent Act

In *Le Roy v. Tatham*, one of the earliest § 101 cases, the Court ruled that a new property of lead alloy used in pipe by itself was not patent eligible.[195] It reasoned that a "principle, in the abstract, is a fundamental truth; an original cause; a motive; [and] these cannot be patented, as no one can claim in either of them an exclusive right."[196] However, the Court clarified that a principle "when practically applied, in the construction of a useful article of commerce or manufacture, is patentable."[197] Thus, the Court created the first of the three exceptions to patent eligibility—the laws of nature—while allowing for practical applications of the principle.[198]

Just one year later, the Court evaluated Samuel Morse's telegraph in describing the patentability of an application of

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191 35 U.S.C. § 112 (2012). *See also* Ropski & Kline, *supra* note 186, at 409.

192 Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).

193 S. Rep. No. 82–1979, at 5 (1952); H. R. Rep. No. 82–1923, at 6 (1952).

194 *Chakrabarty*, 447 U.S. at 309. *See also* Bilski v. Kappos, 561 U.S. 593, 601 (2010).

195 Le Roy v. Tatham, 55 U.S. 156, 176 (1852).

196 *Id.* at 175.

197 *Id.*

198 Efthimios Parasidis, *A Uniform Framework for Patent Eligibility*, 85 TUL. L. REV. 323, 335 (2010).

a natural principle.[199] It invalidated Morse's claim which broadly covered any "effect produced by the use of electromagnetism distinct from the process or machinery necessary to produce it."[200] Although Morse invented just one way of manipulating electric or galvanic current to mark or print intelligible characters, signs, or letters at a distance, his claim sought to protect all applications of electromagnetism to achieve this result.[201] The Court deemed it improper to grant Morse a "monopoly in [using electromagnetism], however developed, for the purpose of printing at a distance."[202] The Court thus reiterated its stance in *Le Roy* that a "newly-discovered principle" was not patentable even if it was cloaked in language that described it as a "process."[203]

Fifty years later, the Court increased the bite of § 101 in *American Fruit Growers v. Brogdex* by determining whether an orange dipped in a borax solution to prevent mold constituted a "manufacture."[204] The Court rejected the assertion that because "[t]he product is a combination of the natural fruit and a boric compound[,] . . . [t]he complete article is not found in nature and is thus an article of manufacture."[205] Instead, the Court concluded:

> Addition of borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property . . . There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.[206]

The decision seemed to discount the patent because the "natural article" (i.e., the orange) was still an orange even

199 O'Reilly v. Morse, 56 U.S. 62 (1853).

200 *Id.* at 120.

201 *Id.* at 112.

202 *Id.* at 113.

203 *Id.* at 117.

204 Am. Fruit Growers v. Brogdex Co., 283 U.S. 1 (1931).

205 *Id.* at 11.

206 *Id.* at 11–12.

though the "added substance" (i.e., the borax) provided protection from mold thus providing a "new and useful" overall product.[207]

Before the 1952 Patent Act, the Court further elaborated on the natural phenomena exception in combination patents in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*.[208] The underlying invention in *Funk Brothers* was created by combining various Rhizobia capable of inoculating the seeds of plants belonging to several cross-inoculation groups.[209] Although each species of Rhizobia was known to protect certain legumes, no one species protected all legumes.[210] Furthermore, attempts to combine various species were unsuccessful because the combinations of Rhizobia inhibited each other.[211] The inventor discovered that certain strains do not exert a mutually inhibitive effect on each other.[212] "Thus, he provided a mixed culture of Rhizobia capable of inoculating the seeds of plants belonging to several cross-inoculation groups" without inhibition.[213] In denying the patent, the Court ruled that while the "methods of selecting and testing non-inhibitive strains are patentable," the product itself was not.[214] The product was not patentable because the inventor did not "create a state of inhibition or of non-inhibition in the bacteria," rather, "[t]heir qualities are the work of nature."[215] Thus, *Funk Brothers* further cemented the natural phenomena judicial exception.

207 1-1 DONALD S. CHISUM, CHISUM ON PATENTS § 1.02 (MB 2017).

208 Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

209 *Id.*

210 *Id.* at 129–30.

211 *Id.*

212 *Id.*

213 *Id.*

214 *Funk Bros.*, 333 U.S. at 130.

215 *Id.*

2. The 1952 Patent Act and the *Benson*, *Flook*, and *Diehr* Trilogy

Two decades after Congress enacted the modern Patent Act in 1952, the Supreme Court waded into the § 101 waters again in *Gottschalk v. Benson*.[216] In *Benson*, the Court denied patent protection for a process of converting binary-coded decimal numbers into pure binary numbers.[217] The claims "purported to cover any use of the claimed method in a general-purpose digital computer of any type."[218] While the Court refused to preclude all computer programs, it noted that a patent could not claim an idea itself.[219] The Court added that "the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself."[220] The *Benson* decision, along with those in *Parker v. Flook* and *Diamond v. Diehr*, outlined the third § 101 exception—the abstract idea.

In *Flook*, the Court rejected the application of an ineligible mathematical formula even when confined to a specific application in an alarm system relating to the catalytic converter process.[221] The inventor asserted that because the algorithm has uses outside of the alarm system it was not attempting to "wholly pre-empt" the formula itself.[222] The Court rejected the argument and noted that a "phenomenon of nature or mathematical formula . . . cannot support a patent unless there is some other inventive concept in its application."[223]

The final case in the abstract idea trilogy came in 1981, just a year before the advent of the Federal Circuit. The patent at issue in *Diehr* concerned a process for curing synthetic rubber "so that the product will retain its shape and be

216 Gottschalk v. Benson, 409 U.S. 63 (1972).

217 *Id.* at 64.

218 *Id.*

219 *Id.* at 71.

220 *Id.* at 71–72.

221 Parker v. Flook, 437 U.S. 584 (1978).

222 *Id.* at 589.

223 *Id.* at 594.

functionally operative after the molding is completed."[224] Although well-known mathematical formulas using time, temperature, and cure relationships existed to determine the optimal time to stop the curing process, the industry previously could not make the necessary computations because no one could properly measure the temperature inside the mold. The patent claimed a process of constantly measuring the temperature inside a mold and automatically feeding it into a computer to repeatedly recalculate the cure time using the formula. In holding the patent valid, the Court explained that the mere use of a mathematical formula did not preclude it from patent protection because the claim had to be considered as a whole.[225]

Through *Benson, Flook,* and *Diehr*, the Court outlined three important considerations for the § 101 analysis. It created the abstract idea exception, stated that a limited application of a § 101 exception is not valid absent some other inventive concept, and established that a patent claim is to be considered as a whole.[226]

3. *Chakrabarty* and Products of Nature

In addition to the abstract idea trilogy, the Supreme Court again took up patentability of living organisms and natural products in 1980 with *Diamond v. Chakrabarty*. The *Chakrabarty* patent described a man-made bacterium capable of digesting oil.[227] In holding that the oil-eating bacterium was patent eligible, the Court ruled that any "product of human ingenuity having a distinctive name, character and use" could be patentable.[228] The Court noted that the proper "distinction was not between living and inanimate things, but between products of nature, whether living or not, and

224 Diamond v. Diehr, 450 U.S. 175, 177 (1981).

225 *Id.* at 187.

226 Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972); *Flook*, 437 U.S. at 590–91; *Diehr*, 450 U.S. at 177.

227 Diamond v. Chakrabarty, 447 U.S. 303, 305 (1980).

228 *Id.* at 309–10 (internal quotation marks omitted).

human-made inventions."[229] This decision led to a specific products of nature category analyzed separately from the other exceptions.[230]

4. Recent Supreme Court Cases: *Bilski*, *Mayo*, *Myriad*, and *Alice*

After the Federal Circuit was created in 1982, the Supreme Court mostly stayed out of the patent eligibility realm until the *Bilski v. Kappos* decision in 2010.[231] In *Bilski*, the Court held that a patent claiming a process of economic hedging in commodities trading was ineligible as an abstract idea.[232] Still, the majority refused to preclude all business method patents and emphasized § 101's role as a threshold requirement, subject to patentability under §§ 102, 103 and 112.[233] The Court also rejected the machine-or-transformation test used by the Federal Circuit in which a process is eligible *only if* "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."[234] Although the outcome was uncontroversial, by leaving the door open to business methods and rejecting the bright line rule developed by the Federal Circuit, the Court arguably did nothing to clarify the § 101 analysis.

The result in *Bilski* did little to narrow patent eligibility any more than the abstract idea trilogy,[235] but the Supreme Court's next decision in *Mayo Collaborative Services. v. Prometheus Labs* severely limited the patenting of diagnostic methods in healthcare.[236] In what was seen as an effort to

229 *Id.* at 313.

230 *See* EXAMPLES: NATURE-BASED PRODUCTS, *supra* note 182.

231 Bilski v. Kappos, 561 U.S. 593 (2010); *see* Golden, *supra* note 31, at 1768.

232 *Bilski*, 561 U.S. at 612.

233 *Id.* at 602, 606–607.

234 *Id.* at 600, 602 (quoting *In re* Bilski, 545 F.3d 943, 954 (Fed. Cir. 2008)).

235 *See* Appendix I.B, *infra*.

236 Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66 (2012). *See* Sanzo, *supra* note 6, at 11 ("The first case in the demise of pa-

prevent patents from tying up "the basic tools of scientific and technological work," the Supreme Court held that a method of diagnostic testing, used to determine the optimal dosage of autoimmune-disease drugs by monitoring certain metabolites in a patient's blood, was directed to a law of nature and therefore invalid.[237] The patent described a process of administering the drug and determining the level of drug metabolites in the patient, wherein the level of metabolites outside of a certain range indicated a need to alter the amount of the drug to enhance efficacy while reducing toxicity.[238]

Importantly, the Court framed the question presented as whether the "patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent eligible processes that *apply* natural laws."[239] The crux of the invention was the specific metabolite to monitor and the range described in the patent claim.[240] The step of administering the drug had already been in practice, and the methods for monitoring metabolite levels were well known in the prior art.[241] The Court additionally stated that the wherein step "simply [told] a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient."[242]

It further noted that "those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately."[243] Although the Court acknowledged the need to look at the whole claim as described in its *Diehr* precedent, it severely limited patent eligibility under § 101 by separating the parts of the claim and essentially applying

tentable gene based diagnostic methods was *Mayo Collaborative Services v. Prometheus Laboratories*.").

237 *Mayo*, 566 U.S. at 71–72.

238 *Id.* at 74.

239 *Id.* at 77.

240 *Id.* at 79.

241 *Id.* at 78–79.

242 *Id.* at 78.

243 *Id.* at 80.

the § 102 novelty analysis to them. Thus, it undermined the statements in *Bilski* that § 101 is to be treated as a threshold requirement.

The Supreme Court followed up its decision in *Mayo* by striking another blow to biotechnology patents in *Molecular Pathology v. Myriad Genetics*.[244] One of the patent claims involved Myriad's synthetically created cDNA, which contained only the amino-acid-coding exon portions of the naturally occurring DNA of the BRCA1 and BRCA2 genes—two genes related to breast cancer.[245] The Court used reasoning similar to that in *Chakrabarty*, which involved a genetically engineered bacterium, to hold that the cDNA was a valid product claim because although the "cDNA retains the naturally occurring exons of DNA . . . it is distinct from the DNA from which it was derived."[246]

The other set of claims at issue gave the inventor the exclusive right to isolate and sequence an individual's BRCA1 and BRCA2 genes.[247] In effect, the patent would give the inventor exclusive rights to use genetic analysis of the BRCA genes for diagnostic purposes. In a short opinion, the Court denied patent eligibility because "Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes."[248] The Court reasoned that Myriad's "principal contribution was uncovering the precise location and genetic sequence" of the genes.[249] Even though isolated DNA encoding BRCA1 and BRCA2 do not exist in nature and all people may have slight differences in the genetic sequences of the genes, the claims were necessarily focused on the *information* encoded in the DNA rather than the particular molecule itself.[250] Thus, the Court likened the claims for the DNA sequence to the bacteria mixture held ineligible in

244 Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107, 2117, 2120 (2013).

245 *Id.* at 2112–13.

246 *Id.* at 2119.

247 *Id.* at 2113.

248 *Id.* at 2117.

249 *Id.*

250 *Id.* at 2118–19.

Funk Brothers rather than the genetically engineered bacterium held eligible in *Chakrabarty*.[251]

Similarly, in order to deny patent protection for innovations that are fundamentally non-technological in nature, the Court ruled in *Alice* that a method, which mitigated settlement risk in financial transactions by using a computer system as a third-party intermediary, was invalid for being directed to an abstract idea.[252] In so doing, it applied the two-step framework suggested in *Mayo* for distinguishing a patent-ineligible concept, as opposed to an *application* of the patent-ineligible concept.[253]

In step one, a court must determine whether a patent claim at issue is "directed to" one of three patent ineligible concepts: law of nature, natural or physical phenomenon, or abstract idea. If the answer is yes, the court must then search for an "inventive concept" that transforms the nature of the claim into a patent-eligible application.[254] In *Alice*, the Court—in another short opinion—summarily found that the patent claims were directed to the abstract idea of intermediated settlement.[255]

For the second step, it ruled that "method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention."[256] Because this did not add anything of "substance" to the underlying abstract concept, which had been done in the prior art by humans, the claims were held patent-ineligible.[257] The Supreme Court's decisions in *Mayo* and *Alice* have left the patent eligibility criterion unclear at best.[258]

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[251] *Id.* at 2118.

[252] Alice Corp. v. CLS Bank Int'l, 134 S.Ct. 2347, 2350–51 (2014).

[253] *Id.* at 2356.

[254] *Id.*

[255] *Id.*

[256] *Id.* at 2357.

[257] *Id.* at 2360–61.

[258] Golden, *supra* note 31, at 1771; *see also* Mark A. Lemley et al., *Life After* Bilski, 63 STAN. L. REV. 1315, 1316 (2011) ("Put simply, the problem is that no one understands what makes an idea 'abstract,' and hence ineligible for patent protection.").